Response to Office Action dated December 29, 2008

REMARKS

The Office Action dated December 29, 2008 has been reviewed. Claims 81-100 were pending in the application. Independent claims 81 and 95 have been amended to more clearly recite the inventive concepts therein. Claims 89 and 98 are have been canceled. For the reasons set forth below, Applicant respectfully submits that the claims are in condition for allowance, and respectfully requests reconsideration and withdrawal of each and every rejection.

I. Amendments and Exemplary Support

Independent claims 81 and 95 have been amended to specify that the tubular sleeve is "capable when lengthened of gripping a tube to exert a compressive gripping force evenly distributed around the tube and along a length of the tube such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force" and to specify that the wall of the sleeve "includes a plurality of filaments helically woven"

Applicant respectfully submits that the amendment adds no new matter. Support for the amendments can be found throughout the application as filed, for example, on page 7, lines 23-24; page 13, lines 18-24; and FIGS. 3-8.

II. Claims 1-90, 92-93, and 95-100 are Novel over Woods et al.

The Action rejected claims 81-90, 92-93, and 95-100 under 35 U.S.C. §102(5) as being anticipated by Woods et al. (US 4,583,534). Applicant respectfully disagrees.

Woods does not appear to disclose: "medical or surgical fastener for securing a tube to a patient," "a sterile tubular sleeve," or "a plurality of filaments helically woven," as recited in independent claims 81 and 95 (and therefore dependent claims 82-90, 92-93, and 96-100). Woods is directed to a collapsible chain mail "structure utilizing a plurality of hollow X-sections connected together by a rope threaded through each leg [of the X-sections]." *Abstract*. Woods discloses an orthopedic prosthetic device (brace), and does not appear to suggest or even consider fastening or securing a tube to a patient. Similarly, Woods does not appear to suggest or even consider that the brace could be made sterile. It would seemingly make little sense for

Response to Office Action dated December 29, 2008

such a brace to be made sterile, as it is expressly designed to be an external brace and makes no apparent mention of catheters or other uses in which a sterile tubular sleeve or even sterilization would be desirable. Further, Woods does not appear to disclose a plurality of filaments helically woven. Instead, Woods discloses a plurality of "articulated hollow X-sections" each with two elongated members that are hinged to one another and are hollow in the center to permit a rope or wire to pass through and connect adjacent X-sections together. *See* col. 4, lines 1-25; FIGS. 11-16. As illustrated in FIGS. 11, 12, and 15, the only crossings between adjacent ropes or wires is within *separate* members of an individual X-sections.

Additionally, Woods does not appear to disclose a tubular sleeve that is "capable when lengthened of gripping a tube to exert a compressive gripping force . . . such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force," as recited in independent claims 81 and 95 (and therefore dependent claims 82-90, 92-93, and 96-100). Woods describes that the brace has two configurations: (1) a flexible configuration in which the structure is "completely flexible" and (2) a rigid configuration in which the assembly is "rigid as a solid tube" or where "the entire assembly [is] rigid within each sections structural limitations." Col. 2, lines 21-35 (emphasis added). As such, the device of Woods does not appear to have the claimed correlation between length and compressive gripping force. Instead, Woods' device appears to merely become rigid enough "to support weight." Col. 2, line 20. Even if Woods' device provides some incidental compressive gripping force, it does not appear to do so in the claimed fashion. "When tension is applied to the rope each section is brought into contact with mating ends of the next section creating a *fixed* condition " Col. 2, lines 31-33 (emphasis added). Specifically, the shape and length of the Woods' device, when in the rigid state, depends entirely on the size of the X-sections: "a variable diameter tube . . . is accomplished by changing the size of the X-sections at the appropriate location, either increasing or decreasing the length of the connecting members." Col. 2, lines 36-40. As shown in FIGS. 11 and 12, the X-sections are fixed an non-adjustable in length – and therefore must be replaced or interchanged to vary the size or shape of the Woods device. As such, the Woods device does not appear to be capable "when lengthened of gripping a tube to exert a compressive gripping force ... such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force."

Response to Office Action dated December 29, 2008

Applicant therefore respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) over Woods et al.

III. Claims 81-100 are Non-Obvious and Patentable over Sobin and Delk

The Action rejected claims 81-100 under 35 U.S.C. §103(a) as being unpatentable over Sobin et al. (US 4,509,877) in view of Delk et al. (US 5,292,312). Applicant respectfully disagrees.

Delk is directed to a "medical conduit holder for securing medical conduits to the skin of a patient." *Abstract*. Delk includes a strap with a wide end 39, a narrow end 38, and a slot 37. To hold a conduit or group of conduits, the strap is wrapped around the conduit or group of conduits, the narrow end 38 passed through the slot, and the wide end 39 and narrow end 38 are both attached *in fixed relation* to a base plate 20, such as with VELCRO. *See* FIGS. 1 and 5-6; col. 6, line 1 – col. 8, line 7. The strap has a central portion 35 that contacts the conduit or group of conduits when in use. This "central portion 35 . . . is a high friction or tacky type material layer . . ." Col. 7, lines 20-22. As such, Delk prevents slipping with friction or tackiness.

Delk does not appear to disclose a fastener having "a sterile tubular sleeve of variable length (as noted in the Action)," "a plurality of filaments helically woven to define a plurality of openings," or "a sleeve capable when lengthened of gripping a tube to exert a compressive gripping force evenly distributed around the tube and along a length of the tube such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force," as recited in independent claims 81 and 95 (and therefore dependent claims 82-94, and 96-100). Specifically, even if Delk can be considered to disclose a sleeve when the strap is wrapped around a conduit, it is not variable in length. Neither does the strap of Delk appear to be perforated or foraminous, nor to have a plurality of filaments helically woven to define a plurality of openings. Even if Delk's strap were considered a sleeve, it is incapable of applying an evenly distributed compressive gripping force such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force. Delk's device is neither capable of lengthening in the claimed manner, nor of increasing an evenly distributed compressive gripping force responsive to movement of a tube.

Response to Office Action dated December 29, 2008

The Action seeks to supply these many deficiencies with Sobin. Sobin is directed to a tapered torque strain relief coupling for "strain relief for the point of attachment of a flexible member to a rigid member." *Abstract*. Sobin *requires* a flexible member with a weave that varies along its length. For example, Sobin teaches that "the end of a flexible member, at its point of attachment to a rigid member, is enclosed within a plurality of braided strands . . . [that] are very closely or narrowly woven at the point of attachment, and are more openly or widely woven as the distance from the point of attachment increases." Col. 3, lines 47-52.

The proposed modification of Delk with Sobin is improper because it would change the principle of operation of Delk, and of Sobin. *See In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP § 2143.01(VI). Specifically, Delk uses a strap to grip a conduit, but Sobin uses a braid to relieve strain and is not adapted for gripping anything. Modification of Delk with the braid of Sobin would require a completely different structure than used in Delk, and would further require modification of the Sobin braid to perform an entirely different function from that in Sobin. As in *In re Ratti*, this "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352. As such, Applicant respectfully submits that the proposed modification of Delk with Sobin is improper.

There is no motivation to modify Delk with Sobin. Delk is directed to a medical conduit holder for securing medical conduits to the skin of a patient. In contrast, Sobin is directed to a strain relief device – *not* a device for securing or connecting. For example, Sobin teaches that the cable 1 (flexible member) is attached to the plug 3 (rigid member) by means of a clamp 5. See FIG. 1; col. 4 lines 39-44. Sobin attempts to reduce lateral strains and torque at the point of connection of the flexible member to the rigid member. There is no need – *and therefore no motivation* – to modify the Delk device because lateral strains and torque are of little consequence when a conduit is connected to the skin of the patient. Specifically, there is no need to protect the conduit at the point of connection to skin because the skin or the connection to the skin is far more susceptible to damage than the conduit.

Delk itself illustrates that a person of ordinary skill in the art would not combine these teachings. Delk is directed to securing medical conduits to the skin of a patient, an art that is at

Response to Office Action dated December 29, 2008

least similar to that of the present application. At the time Delk filed his application, the Sobin reference was available and had been available for over 7 years. Nevertheless, neither Delk nor apparently any other person of ordinary skill in the art made such modifications or combinations prior to the present Applicant.

Even if Delk were modified with Sobin, it would not include every element of the claims. As the Office is aware, all claim limitations must be considered. See MPEP 2143.03. Sobin fails to disclose or suggest a sleeve that is capable when lengthened of gripping a tube to exert a compressive gripping force evenly distributed around the tube and along a length of the tube. For example, the deliberately varied braid of the Sobin device is not uniform along its length and, even if stretched to contact a conduit, would be incapable of exerting a compressive gripping force evenly distributed along a length of the tube. Further, any speculative modification of Sobin to reduce the variation of the braid would be improper because it would render the Sobin device unsuitable for its explicitly stated purpose. See MPEP 2413.01(V). Additionally, nothing in the Sobin reference suggests that the Sobin device, even if stretched to contact a conduit would be capable of gripping the conduit such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force.

For the foregoing reasons, Application respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) over Delk in view of Sobin.

Response to Office Action dated December 29, 2008

IV. Conclusion

The foregoing is intended to be a complete response to the Office Action dated December 29, 2008. In view of the foregoing, Applicant respectfully submits that claims 81-100 are in condition for allowance, and respectfully requests reconsideration and withdrawal of the rejections and allowance of the claims.

The Examiner is invited to contact Applicant's agent at (512) 536-3083 with any comments or questions in order to expedite the resolution of any remaining issues.

Respectfully submitted,

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